

## **REMARKS**

### ***Summary of Changes Made***

The undersigned would like to thank Examiner John Pak for his time on the telephone several times over a period of months, most recently 27 June 2008, to discuss various issues of the application.

The application was filed with 11 claims. In a preliminary amendment filed together with the application, claims 12-17 were added. In another amendment, claims 9-11 were canceled and claims 1-8 and 12-17 were amended, while claims 18-21 were added. In the present amendment, Claim 2 has been amended to include the limitation that the iron-carbohydrate complex has an average molecular weight of 80,000 to 400,000. Claims 4 and 12 are amended to address a grammar issue.

It was stated in the previous amendment, filed 5 February 2008, that a terminal Disclaimer had been filed. This statement was in error, and no terminal disclaimer has been filed and none is included herewith. Applicants note for the record that certain claims of commonly owned copending Application Ser. No. 11/815,568 have been canceled to overcome a provisional double patenting rejection herein, which is more fully described hereinbelow. Accordingly, claims 1-8 and 12-21 (18 claims) remain pending in the application. No new matter is added by this amendment.

### ***Claim Objections - 37 C.F.R. §1.75(c)***

The Examiner objected to claims 2-6, 12-17, and 20-21 for improper dependent form as failing to further limit the subject matter of a previous claim. The Examiner contends that claim 2, a method claim, recites a method of producing the complex of claim 1. However, claim 2 lacks language that ensures the production of a complex having a molecular weight of 80,000 to 400,000, as recited in claim 1. The remaining claims under this rejection all ultimately depend from claim 2.

The Examiner will note that claim 2 has been amended to fully independent form to recite that the claimed process produces "a water soluble iron carbohydrate complex having a weight average molecular weight (Mw) of 80,000 to 400,000."

Paragraph 22 of the instant specification (as set forth in U.S. Pat. App. Pub. No. 2006/0205691 clearly discloses that the inventive method results in complexes having a weight average molecular weight of 80,000 to 400,000. Further, the Examiner will note that

all examples of the inventive process result in complexes having molecular weights within this claimed range.

***Claim Rejections – Non Statutory Obviousness-Type Double Patenting***

Claims 1-4, 7, 8, 12, 18, and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-16, 26 and 27 of commonly owned copending Application No. 11/815,568 in view of Thaburet and Dokic. The Examiner contends that Claim 26 of the copending application sets forth a process of making an iron (III) maltodextrin complex comprising contacting maltodextrin having a DE of 5-37 with an aqueous hypochlorite solution having a pH of greater than 7 to form a reaction mixture and contacting the mixture with an aqueous iron (III) salt solution. Claims 13 and 16 of the copending application allegedly set forth a medicament comprising a complex of an oxidation product of at least one maltodextrin with iron (III) in various medication forms. The discussion of the secondary references is incorporated herein by reference. The Examiner concludes that the skilled artisan would have found it obvious to use the known processes for oxidizing carbohydrates, including dextrans, and that carbohydrates and oxidized dextrans are also known for delivering iron to subjects in need thereof.

The Examiner will note that a Preliminary Amendment has been filed in the cited copending application (11/815,568), a copy of which, together with the filing receipt therefor, (6 pages total) is enclosed herewith. The EFS ID for the filing receipt of said Preliminary Amendment is 3870932. The Preliminary Amendment in the copending application cancels claims 13-16, 26, and 27. Thus it is believed the grounds for such rejection herein have been removed, rendering moot the provisional double patenting rejection.

In the Amendment filed 5 February 2008, it was stated that a terminal disclaimer had been filed with respect to the cited copending application. This is in error as no terminal disclaimer was actually filed, and none is included here.

***Translation of CN 2002061- (HCAPLUS Abstract 2003:135397)***

The Examiner has kindly provided a full English translation of CN 20020612, previously cited as HCAPLUS Abstract 2003:135397. Applicants expressly acknowledge that the Examiner has not further applied the reference as a result of the translation. It is hence believed that the argumentation in the Amendment filed 5 February 2008 has

overcome the rejection of claims 1-8 and 11-17 are 35 U.S.C. 103(a) as unpatentable over HCAPLUS Abstract 2003:135397 ("HCAPLUS2") in view of Thaburet and Dokic.

In light of the cancellation of claim 11, Applicants state for the record their belief that claims 1-8 and 12-17 are patentable over the above-mentioned art combination (HCAPLUS2/Thaburet/Dokic).

### **ERROR IN PUBLISHED PATENT APPLICATION**

Applicants state for the record that the publication of the instant application, U.S. Pat. App. Pub. No. 2006/0205691 contains typographical errors introduced at the publication stage, errors which do not appear in the official record.

Paragraph 42 thereof currently reads, in part, "in a range of 10.85" and should read **"in a range of 1:0.85."** That is, the text of paragraph 42 should be identical to that in paragraph 36. Further, paragraph 56 contains the erroneous "1118 kDa," which should be **"118 kDa."**

### **CONCLUSION**

Based on the foregoing, the Applicants respectfully request entry of the instant amendment and a Notice of Allowability for claims 1-8 and 12-21. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application. If there are any additional fees resulting from this communication, please charge the same to our Deposit Account No. 18-0160, our Order No. GIL-15940.

Respectfully submitted,

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By

  
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## Electronic Acknowledgement Receipt

<b>EFS ID:</b>	3870932
<b>Application Number:</b>	11815568
<b>International Application Number:</b>	
<b>Confirmation Number:</b>	9041
<b>Title of Invention:</b>	Use Of Iron(III) Complex Compounds
<b>First Named Inventor/Applicant Name:</b>	Jessica Tanner-Baumgartner
<b>Customer Number:</b>	07609
<b>Filer:</b>	Kenneth A. Clark/Kathryn Kallay
<b>Filer Authorized By:</b>	Kenneth A. Clark
<b>Attorney Docket Number:</b>	GIL-17476
<b>Receipt Date:</b>	02-SEP-2008
<b>Filing Date:</b>	03-JAN-2008
<b>Time Stamp:</b>	12:20:11
<b>Application Type:</b>	U.S. National Stage under 35 USC 371

### Payment information:

Submitted with Payment	no
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### File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		gil17476prelim.pdf	289928 0a32ea9587775d0308012cf81ef27de3d13fb9d3	yes	4

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Preliminary Amendment	1	1
	Claims	2	3
	Applicant Arguments/Remarks Made in an Amendment	4	4

**Warnings:**

**Information:**

<b>Total Files Size (in bytes):</b>	289928
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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

**New Applications Under 35 U.S.C. 111**

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

**National Stage of an International Application under 35 U.S.C. 371**

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

**New International Application Filed with the USPTO as a Receiving Office**

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application. No.	:	11/815,568
Confirmation. No.	:	9041
Applicant(s)	:	Jessica Tanner-Baumgartner et al.
Filed	:	3 January 2008
Title	:	Use of Iron(III) Complex Compounds
TC/A.U.	:	1796
Examiner	:	none
Docket No.	:	GIL-17476

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PRELIMINARY AMENDMENT "B"**

Sir:

Prior to examining the application and calculating the filing fee, please amend the above-identified application as follows:

- **Amendments to the Claims** are reflected in the Listing of Claims, which begins on page 2 of this paper.
- **Remarks/Arguments** begin on page 4 of this paper.

## **AMENDMENTS TO THE CLAIMS**

The following listing of claims will replace all prior versions, and listings, of claims in the application:

### **Listing of Claims**

Claims 1-16 (canceled)

Claim 17 (currently amended): A method of improving brain function comprising administering to a patient a medication comprising an iron(III) compound selected from the group consisting of iron(III) polymaltose and an iron(III)maltodextrin complex, the iron(III) maltodextrin complex comprising a complex of an oxidation product of one or more maltodextrins with iron(III), wherein the ~~pateient~~ patient may be of any age.

Claim 18 (previously presented): The method of claim 17, wherein the iron(III) compound is an iron(III) polymaltose complex having a molecular weight ( $M_w$ ) of 20,000 to 500,000.

Claim 19 (previously presented): The method of claim 17, wherein the iron(III) compound is an iron(III) polymaltose complex having a molecular weight ( $M_w$ ) of 30,000 to 80,000.

Claim 20 (previously presented): The method of claim 17, wherein the iron(III) compound is an iron(III) maltodextrin complex having a molecular weight ( $M_w$ ) of 30,000 to 500,000.

Claim 21 (previously presented): The method of claim 17, wherein the medication is administered intravenously, intramuscularly, or orally.

Claim 22 (previously presented): The method of claim 17, wherein the patient is selected from the group consisting of (a) anemic patients having iron deficiency, (b) non-anemic patients having iron deficiency, (c) non-anemic patients not having iron deficiency, and (d) patients with no iron deficiency.

Claim 23 (previously presented): A method of improving at least one of neutrophil level, antibody level, and lymphocyte function as measured by lymphocyte reaction to phytohemoglobin, the method comprising administering to a patient a medication comprising an iron(III) compound selected from the group consisting of iron(III) polymaltose and an iron(III)maltodextrin complex, the iron(III) maltodextrin complex comprising a complex of an oxidation product of one or more maltodextrins with iron(III).

Claim 24 (previously presented): The method of claim 23, wherein the iron(III) compound is an iron(III) polymaltose complex having a molecular weight ( $M_w$ ) of 20,000 to 500,000.

Claim 25 (previously presented): The medication of claim 23, wherein the iron(III) compound is an iron(III) polymaltose complex having a molecular weight ( $M_w$ ) of 30,000 to 80,000.

Claims 26-27 (canceled)

Claim 28 (new): A method of improving immune defense comprising administering to a patient a medication comprising an iron(III) compound selected from the group consisting of iron(III) polymaltose and an iron(III)maltodextrin complex, the iron(III) maltodextrin complex comprising a complex of an oxidation product of one or more maltodextrins with iron(III), wherein the patient may be of any age.



## **REMARKS**

### ***Summary of Changes Made***

The application was filed with claims 1-12. Claims 1-12 were canceled in a previous amendment. Claims 13-16, 26, and 27 are canceled herein to overcome a double-patenting rejection in commonly owned copending application number 10/531,895 (Docket No. GIL-15940). New claim 28 is added to round out Applicant's claim coverage, and claim 17 is amended to correct a typographical error. Support for claim 28 is found in the subject matter of canceled claim 13 and claim 17. Thus, claims 17-25 and 28 (10 claims) remain pending in the application. No new matter is added hereby.

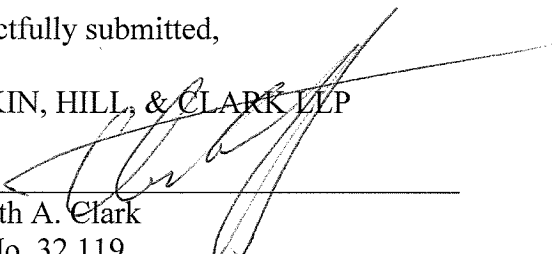
## **CONCLUSION**

In light of the foregoing, it is respectfully submitted that the present application, is in condition for allowance and notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge the same to our Deposit Account No. 18-0160, our Order No. GIL-17476.

Respectfully submitted,

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